

Shining light on medical 'writers'

By LOU GELFAND

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Documents showing that pharmaceutical giant Wyeth paid ghostwriters to produce medical journal articles favorable to the company's Prempro hormone replacement therapy have become public.

One such article in the American Journal of Obstetrics and Gynecology was published even after a federal study, called the Women's Health Initiative, linked Prempro to breast cancer.

At the height of hormone therapy in 2001, more than 126 million U.S. prescriptions for such drugs were written. Sales in that year, primarily by Wyeth, were \$3 billion. After results of the federal study became public, sales of hormone drugs plummeted.

The documentation comes from a committee chaired by Sen. Charles Grassley, R-Iowa. It shows that Wyeth executives came up with ideas for medical journal articles, titled them, drafted outlines, paid writers to draft the manuscripts, recruited academic authors and identified publications to run the articles -- all without disclosing the company's roles to editors or readers.

In a Dec. 12 story, the New York Times quoted Grassley's letter to Wyeth CEO Bernard Pousot: "Any attempt to manipulate the scientific literature, that can in turn mislead doctors to prescribe drugs that may not work and/or cause harm to their patients, is very troubling."

The released documents included a Wyeth report showing 10 articles in which the manuscripts were completed by the company before they were sent to the putative author for review.

Grassley contends that expert authors whose names appeared on the articles became involved only after outlines or drafts of the reports had been written.

Such activities would seem to run afoul of medical journal guidelines. The International Committee of Journal Editors says authorship means "substantive intellectual contributions."

The World Association of Medical Editors says ghost authorship -- which it defines as a substantial contribution not mentioned in the manuscript -- is "dishonest and unacceptable."

The May 2003 article supporting Prempro was signed by Dr. John Eden, director of the Menopause Center in Sydney, Australia. According to documents released by Grassley, Eden had the outline and draft manuscript written for him.

Grassley's committee earlier released documents showing that psychiatrist Dr. Charles Nemeroff of Emory University earned more than \$2.8 million in consulting arrangements with drugmakers from 2000 to 2007, but failed to report at least \$1.2 million of it to the university, thus violating federal research rules.

Grassley has taken the lead in the Senate on issues of medical ethics. He cosponsored legislation requiring all drug and medical device companies to post their financial relationships with doctors on a national website.

The more sunshine in the medical arena, the better.

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